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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/053,975

01/18/2002

Limin Li

FUNC-0020-UT1

5176

22506 7590 07/23/2008

JAGTIANI + GUTTAG  
10363-A DEMOCRACY LANE  
FAIRFAX, VA 22030

EXAMINER

FETTEROLF, BRANDON J

ART UNIT

PAPER NUMBER

1642

MAIL DATE

DELIVERY MODE

07/23/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

***Response to the Amendment***

The Amendment filed on 06/17/2008 in response to the previous Final Office Action (3/17/2008) is acknowledged, but not has been entered. The amendment has not been entered because it contains claim limitation which have not been previously searched or considered. For example, Claim 4 has been amended to recite the limitation "..., and wherein said epitope is found in amino acid residues 50-140." As such, this claim limitation would require further consideration with respect to 112 1st paragraph, New Matter, as well as, the prior art.

Claims 1, 4-16, 22-25, 31-32 and 37-50 are pending.

Claims 7-16, 22-25, 31-32, 37-42 and 44-45 are withdrawn from consideration as being drawn to non-elected inventions.

Claims 1, 4-6, 43 and 46-50 are currently under consideration.

**Rejections Maintained:**

As Applicant's arguments appear to be solely drawn to the currently amended claims, such arguments have not been considered. As such, the following rejections are maintained:

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-6, 43 and 46-50 remain rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (IDS, US 5,891,668, 1999) as evidenced by Pornillos et al. (The EMBO Journal 2002; 21: 2397-2406).

Li. et al. teach antibodies which have been raised to normal or mutated forms of TSG101 (column 8, line 59-63). Specifically, the patent teaches antibodies that specifically recognize the coiled domain, leucine zipper and proline rich domains of TSG101 (column 8, lines 64 to column 9, line 4). Moreover, the patent teaches that the antibodies include, but are not limited to, polyclonal antibodies and monoclonal antibodies (column 9, lines 5-21). With regards to TSG101, Li et al.

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provide both the mouse TSG101 and the human homolog (column 3, lines 26-38, see below, human homolog). Although the reference does not specifically teach that the antibody binds specifically to an epitope in the ubiquitination-regulating domain of TSG101 protein found in amino acid residues 1-250 of SEQ ID NO: 1, the claimed limitation does not appear to result in a manipulative difference between the prior art because as taught by the specification (page 10, *Overview*) and as evidenced by Pornillos et al., the proline rich domain (referred to as PRD) and at least a portion of the coiled domain (referred to as COIL) lies within amino acid residues 1-250 of SEQ ID NO: 1 (page 2398, Figure 1A). Thus, the claimed antibody appears to be the same as the prior art. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989). Lastly, the transitional term “comprising”, which is synonymous with “including,” “containing,” or “characterized by,” is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. As such, the limitation that the antibody binds to an epitope in the ubiquitination regulating domain of TSG101, wherein the ubiquitination regulating domain “comprises” amino acid residues 50-140 or 1-140 of SEQ ID NO: 1, does not appear to result in difference between the antibodies taught by Li et al. which specifically binds to the proline rich domain of TSG101 for the reasons set forth above.

Patent No. 5891668

APPLICANT: LI, Limin

APPLICANT: COHEN, Stanley N

US-08-670-274B-4

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Query Match          97.8%; Score 2002; DB 2; Length 380;
Best Local Similarity 100.0%; Pred. No. 3e-155;
Matches 380; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy      11 MVSKYKYRDLTVRETVNVITLYKDLKPVLD SYVFNDGSSRELMNLTGTIPVPYRGNTYNI 70
         |||
Db      1  MVSKYKYRDLTVRETVNVITLYKDLKPVLD SYVFNDGSSRELMNLTGTIPVPYRGNTYNI 60

Qy      71 PICLWLLDTYPYNPPICFVKPTSSMTIKTGKHVDANGKIYLPYLHEWKHPQSDLLGLIQV 130
         |||
Db      61 PICLWLLDTYPYNPPICFVKPTSSMTIKTGKHVDANGKIYLPYLHEWKHPQSDLLGLIQV 120

Qy      131 MIVVFGDEPPVFSRPISASYPPYQATGPPNTSYMPGMPGGISPYSGYPNPSGYPGCPY 190
         |||
Db      121 MIVVFGDEPPVFSRPISASYPPYQATGPPNTSYMPGMPGGISPYSGYPNPSGYPGCPY 180
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Qy      191 PPGGYPYPATSSQYPSQPPVTTVGPSRDGTISEDITIRASLISAVSDKLRWRMKEEMDRAQ 250
      |||
Db      181 PPGGYPYPATSSQYPSQPPVTTVGPSRDGTISEDITIRASLISAVSDKLRWRMKEEMDRAQ 240

Qy      251 AELNALKRTEEDLKKGHQKLEEMVTRLDQEAQVVDKNIELLKKKDEELSSALEKMQSE 310
      |||
Db      241 AELNALKRTEEDLKKGHQKLEEMVTRLDQEAQVVDKNIELLKKKDEELSSALEKMQSE 300

Qy      311 NNDIDEVVIPTAPLYKQILNLYAEENAIEDTIFYLGEALRRGVLDLDVFLKHVRLLSRKQ 370
      |||
Db      301 NNDIDEVVIPTAPLYKQILNLYAEENAIEDTIFYLGEALRRGVLDLDVFLKHVRLLSRKQ 360

Qy      371 FQLRALMQKARKTAGLSLDLY 390
      |||
Db      361 FQLRALMQKARKTAGLSLDLY 380

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Claims 1, 4-6, 43 and 46-50 remain rejected under 35 U.S.C. 102(b) as being anticipated by Brie et al. (US 5,892,016, 1999, *of record*).

Brie *et al.* teach a purified protein having an amino acid sequence having 100% identity to the amino acid sequence set forth in SEQ ID NO: 1 (Figures 1A-1B, *see below*). The patent further teaches antibodies including, but not limited to, polyclonal, monoclonal and chimeric which bind specifically to the polypeptide (column 17, line 15 to column 18, line 16). Furthermore, Brie et al. disclose that the antibodies can be used as a pharmaceutical agent for the prevention and or treatment of disease associated with expression of the polypeptide (column 16, lines 56-60). Although the reference does not specifically teach that the antibody binds to a polypeptide comprising a ubiquitination-regulating domain, the claims are drawn to the product *per se* and inherently, such an antibody would bind to a polypeptide comprising a ubiquitination-regulating domain. Thus, the claimed peptide appears to be the same as the prior art. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

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OS      Homo sapiens.
PN      US5892016-A.
PD      06-APR-1999.
PF      23-JAN-1997;    97US-00786999.
PR      23-JAN-1997;    97US-00786999.
PA      (INCY-) INCYTE PHARM.
PI      Brie SL, Goli SK;
SQ      Sequence 390 AA;

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Query Match 100.0%; Score 2047; DB 2; Length 390;

Best Local Similarity 100.0%; Pred. No. 6.7e-149;  
Matches 390; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy	1	MAVSESQLKKMVSKYKYRDLTVRETVNVITLYKDLKPVLD SYVFNDGSSRELMNLTGTIP	60
Db	1	MAVSESQLKKMVSKYKYRDLTVRETVNVITLYKDLKPVLD SYVFNDGSSRELMNLTGTIP	60
Qy	61	VPYRGNTYNIPICLWLLDTPYNPPICFVKPTSSMTIKTGK HVDANGKIYLPYLHEWKHP	120
Db	61	VPYRGNTYNIPICLWLLDTPYNPPICFVKPTSSMTIKTGK HVDANGKIYLPYLHEWKHP	120
Qy	121	QSDLLGLIQVMIVVFGDEPPVFSRPISASYPYPYQATGP PNTSYMPGMPGGISPYPSGYPP	180
Db	121	QSDLLGLIQVMIVVFGDEPPVFSRPISASYPYPYQATGP PNTSYMPGMPGGISPYPSGYPP	180
Qy	181	NPSGYPGCPYPYPGGPYPATSSQYPSQPPVTTVGPSRD GTISED TIRASLISAVSDKLRW	240
Db	181	NPSGYPGCPYPYPGGPYPATSSQYPSQPPVTTVGPSRD GTISED TIRASLISAVSDKLRW	240
Qy	241	RMKEEMDRAQAELNALKRTEEDLKKGHQKLEEMVTRL DQEVAEVDKNIELLKKKDEELSS	300
Db	241	RMKEEMDRAQAELNALKRTEEDLKKGHQKLEEMVTRL DQEVAEVDKNIELLKKKDEELSS	300
Qy	301	ALEKMENQSENNDIDEVIIPTAPLYKQILNLYAEENAIED TIFYLGEALRRGVIDLDVFL	360
Db	301	ALEKMENQSENNDIDEVIIPTAPLYKQILNLYAEENAIED TIFYLGEALRRGVIDLDVFL	360
Qy	361	KHVRLLSRKQFQLRALMQKARKTAGLSLDY	390
Db	361	KHVRLLSRKQFQLRALMQKARKTAGLSLDY	390

Therefore, No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON J. FETTEROLF whose telephone number is (571)272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Brandon J Fetterolf

Primary Examiner

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/Brandon J Fetterolf/

Primary Examiner, Art Unit 1642